K113802

APR 16 2012

510(k) Summary: Escalate™ Laminoplasty System	
Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Ms. Simona Voic Sr. Regulatory Affairs Project Manager Phone: 908-522-3482/ Fax: 201-760-8482 Email: simona.voic@stryker.com
Date Prepared	April 13, 2012
Trade Name	Escalate™ Laminoplasty System
Proposed Class	Class II
Classification Name and Number	Spinal interlaminal fixation orthosis, 21 CFR §888.3050
Product Code	NQW
Predicate Devices	The Escalate™ Laminoplasty System was shown to be substantially equivalent to the devices listed below: • Medtronic Centerpiece™ Plate Fixation System (K050082) • Synthes Arch™ Fixation System (K032534)
Device Description	The Escalate™ System consists of a comprehensive set of implants and instruments designed for a systematic approach to cervical laminoplasty procedures. The system features an expandable laminoplasty plate, a hinge ("Base") plate, bone screws for fixation, and a set of instrumentation to assist in the implantation and removal of the implants. The plates have screw holes, which allow for attachment to the vertebral body. The screws to be used with the plates are available in a variety of lengths and diameters and are designed to match the anatomical requirements. The Escalate™ Laminoplasty plates and screws are manufactured from Titanium alloy and will be provided non-sterile.

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510(k) Summary: Escalate™ Laminoplasty System	
Intended Use/ Indications for Use	The Escalate™ Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3-T3) in laminoplasty procedures. The system is intended to hold the lamina open following a laminoplasty procedure.
Summary of the Technological Characteristics	The technological characteristics of the Escalate™ Laminoplasty System are the same or similar to the predicate devices commercially distributed.
Performance Data	The performance testing conducted to demonstrate substantial equivalence to the predicate devices included: static and dynamic compression loading (modified ASTM 1717-11a), screw driving insertion torque (ASTM F543-07), screw removal torque (ASTM F543), screw torque to failure (ASTM F543-07), and axial screw pull-out (ASTM F543-07). The performance data verifies that the subject devices are substantially equivalent to the predicate devices currently on the market and have met all mechanical test requirements based on the engineering rationale.
Substantial Equivalence	The Escalate™ Laminoplasty System was determined to be substantially equivalent to the above referenced predicate devices. The subject system does not present any new issues of safety and effectiveness.
Conclusion	The Escalate™ Laminoplasty System is substantially equivalent to its predicate devices. Mechanical testing as well as other supporting information sufficiently demonstrates the substantial equivalence of the Escalate™ Laminoplasty System to the other laminoplasty fixation systems. Based on this information, the subject system does not raise any new issues regarding the safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stryker Spine
% Ms. Simona Voic
Senior Regulatory Affairs Project Manager
2 Pearl Court
Allendale, New Jersey 07401

APR 16 2012

Re: K113802
Trade/Device Name: Escalate™ Laminoplasty System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: NQW
Dated: March 22, 2012
Received: March 23, 2012

Dear Ms. Voic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Peter ... mo m ... CLIN DEP DIR

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K___113802_____

Device Name: Stryker Spine Escalate™ Laminoplasty System

Indications For Use:

The Escalate™ Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3-T3) in laminoplasty procedures. The system is intended to hold the lamina open following a laminoplasty procedure.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113802